

Attorney Docket No.: KUZ-0022
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Serial No.: 10/527,710
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REMARKS

Claims 1-5 and 8-19 were pending in the instant application. Claims 1 and 8 have been amended. New claim 20 has been added. Support for these amendments is provided in the specification, for example, at page 1, lines 5-6, page 1, line 15 through page 2, line 14, page 4, lines 13-22, page 21, line 15 through page 22, line 4 and Figure 1. No new matter is added by these amendments. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 8 and 13-19 under 35 U.S.C. 112, second paragraph

Claims 8 and 13-19 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner suggests that it cannot be determined which specific ingredients are consisting within the pressure sensitive adhesive base because the number and type of percutaneous absorption enhancers are nonlimiting in claims 8 and 13-19 and the genus of compounds taught in the instant disclosure could perform various functions beyond enhancing

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percutaneous absorption in the pressure sensitive adhesive base.

Applicants respectfully traverse this rejection.

MPEP 2173.02 is clear; definiteness of claim language must be analyzed, not in a vacuum, but in light of:

(A) The contents of the particular application disclosure;

(B) The teachings of the prior art; and

(C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

The contents of the particular application at, for example, pages 7-8, make clear the percutaneous enhancers for fentanyl which may be contained in the pressure sensitive adhesive base of the adhesive patch of the present invention.

However, in an earnest effort to advance the prosecution of this case, claim 8 has been amended to depend from claim 1, drawn to "an adhesive patch . . . wherein the pressure-sensitive adhesive base comprises . . .", and to recite "The adhesive patch according to claim 1 wherein the pressure-sensitive adhesive base further comprises a percutaneous absorption enhancer." Support for this

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amendment is provided by teachings of the specification, for example, at pages 7-8.

Withdrawal of this rejection is therefore respectfully requested.

II. Rejection of Claims 8, 9 and 13-19 under 35 U.S.C. 112, first paragraph

Claims 8, 9 and 13-19 are rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. The Examiner suggests that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s) at the time the application was filed had possession of the claimed invention. Specifically, the Examiner suggests that there is no *ipsis verbis* or implied support for the concept of a pressure sensitive adhesive layer consisting of the four elements as set forth in claim 8.

Applicants believe this rejection is now moot in light of the amendments to claim 8 discussed in detail in Section I, *supra*.

Withdrawal of this rejection is therefore respectfully requested.

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III. Rejection of Claims under 35 U.S.C. 103(a)

Claims 1-3, 8, 9, 11, 12, 14-16 and 19 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. (U.S. Patent 6,139,866), Tsuruda et al. (CA 2 424 579), Hirano et al. (U.S. Patent 6,495,159) and Higo et al. (U.S. Patent 5,866,157).

Claims 4 and 17 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al., Higo et al. and Hirano et al. as applied to claims 1-3, 8, 9, 11, 12, 14-16 and 19 and further in view of Urquhart et al. (U.S. Patent 4,031,894).

Claims 5 and 18 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al., Higo et al. and Hirano et al. as applied to claims 1-3, 8, 9, 11, 12, 14-16 and 19 and further in view of Scholz et al. (U.S. Patent 5,750,136).

Claims 10 and 13 have also been rejected under 35 U.S.C. 103(a) as being unpatentable over Chono et al. in view of Tsuruda et al., Higo et al. and Hirano et al. and further in view of Zafforini (U.S. Patent 3,598,122) and further in view of Kochinke (U.S. Patent 5,350,581).

Applicants respectfully traverse these rejections.

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Applicants have amended claim 1, from which all other pending claims ultimately depend, to recite an adhesive patch for maintaining long-term drug efficacy of fentanyl for more than 48 hours. Support for this amendment is provided in the specification at, for example, page 1, lines 5-6, page 4, lines 13-22, page 21, line 15 through page 22, line 4 and Figure 1. Applicants have also amended claim 1 to include the proviso that the adhesive patch does not contain an organic acid salt. Support for this amendment is provided in the specification at, for example, page 1, line 15 through page 2, line 14, wherein ion pair patches containing an organic acid salt are specifically distinguished from patches of the present invention. Further support for this amendment is provided by Examples 1 through 4 disclosed at pages 13-14, none of which include an organic acid salt.

In contrast, the primary reference of these obviousness rejections, namely Chono et al., corresponds to Patent Document 2, JP, A, 10-45570 and is discussed in the instant patent application at page 1, lines 15-18 and page 1, line 26 through page 2, line 8. Chono et al. describes an ion-pair type adhesive patch. As discussed in the specification ion-pair patches are not suitable for maintaining long-term

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drug efficacy exceeding one day. See page 2, lines 4-8 of the instant specification as well as experiments described in Chono et al. at col. 11, lines 1-57 wherein transdermal permeation rates were examined only out to 24 hours.

Accordingly, teachings of Chono et al. provide no reasonable expectation of success with respect to the instant claimed invention reciting an adhesive patch for maintaining long-term drug efficacy of fentanyl for more than 48 hours.

Further, as taught in the specification at pages 1 and 2, ion-pair type adhesive patches such as taught by Chono et al. require an organic acid salt. Specifically, Chono et al. requires sodium acetate. See teachings throughout Chono et al., for example, in the Abstract, col. 1 line 64, col. 2, lines 2, 9, 14 and 18 and col. 3 lines 21-32. Sodium acetate, also commonly referred to as sodium ethanoate, is the sodium salt of acetic acid. Acetic acid, also known as ethanoic acid, is an organic acid which gives vinegar its sour taste and pungent smell. Thus, sodium acetate is an organic acid salt. Claims of the instant application have been amended to specifically exclude from the instant claimed patch organic acid salts. Clearly exclusion of this required element of Chono et al. renders the instant claims unobvious over Chono et al.

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Secondary references of Tsuruda et al. (CA 2 424 579), Hirano et al. (U.S. Patent 6,495,159), Higo et al. (U.S. Patent 5,866,157), Urquhart et al. (U.S. Patent 4,031,894), Scholz et al. (U.S. Patent 5,750,136), Zafforini (U.S. Patent 3,598,122) and Kochinke (U.S. Patent 5,350,581) fail to remedy deficiencies in the primary reference as these references are unrelated to fentanyl administration, and in particular maintaining long-term drug efficacy of fentanyl for more than 48 hours.

Thus, the cited combinations of references fail to establish a prima facie case of obviousness with respect to the instant claimed invention as they provide no reasonable expectation of success that an adhesive patch with no organic acid salt could be used to maintain long-term drug efficacy of fentanyl for more than 48 hours.

Withdrawal of all rejections under 35 U.S.C. 103(a) is therefore respectfully requested.

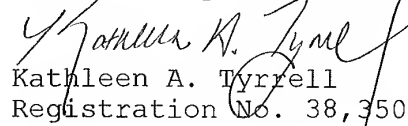
IV. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Actions of record. Accordingly, favorable reconsideration and subsequent

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allowance of the pending claims is earnestly solicited.

Respectfully submitted,


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